

and to avoid sensing in the refractory period. If only a single chamber is being stimulated, this is unproblematical because the stimulation, blanking and sensing can be easily synchronized. When more than one chamber is stimulated, as in multi-chamber pacing, the problem exists that sensing of one chamber may be occurring when a stimulation pulse is generated for a different chamber. To avoid the sensing circuitry for the chamber being sensed from being overwhelmed by the stimulation pulse delivered to the other chamber, it is necessary for the blanking to be effective for the chamber being sensed as well as for the chamber to which the stimulation pulse is being delivered. For the chamber being sensed, this causes an interruption in the sensed signal, and thus there is a "gap" in the sensed IEGM signal from that chamber.

The problem is solved in accordance with the present invention by a multi-chamber pacing system having a signal reconstructing unit that reconstructs the IEGM signal from a chamber being sensed in a blanking interval following delivery of a pacing pulse to a different chamber. Therefore, although the actual sensed IEGM signal will contain a "gap" wherein no signal was sensed due to the blanking interval associated with the stimulation of a different chamber, the signal reconstruction unit is able to reconstruct a complete IEGM signal for the sensed chamber. Conventionally, if such a situation occurred wherein a sensed IEGM signal had a gap therein due to sensing taking place when a blanking interval occurred due to stimulation of a different chamber, that IEGM signal had to be discarded or, if used, might produce an erroneous interpretation, due to the gap therein, when that signal is analyzed. The present invention avoids these problems by always providing a complete IEGM signal, obtained by signal reconstruction, even if the sensed signal

has been sensed during a blanking interval associated with stimulation of a different chamber.

The Mika et al reference has nothing whatsoever to do with the problem of sensing a signal from one chamber during a time when a blanking interval occurs due to the stimulation of a different chamber, and therefore does not provide a person of ordinary skill in the field of cardiac stimulator design with any basis or insight for solving that problem.

The Mika et al reference is directed to a cardiac stimulator that, although generating conventional stimulation pulses and sensing the IEGM signals resulting therefrom, is augmented by the generation of a so-called excitable tissue control signal, referred to as an ETC signal in the Mika et al reference. As explained at column 2, lines 42-47, ETC signals are *not* the same as the conventional stimulation pulses that are delivered to stimulate a contraction, but are instead signals that are delivered *after* a heart chamber has been stimulated, and are intended to influence the electrochemical/electromechanical dynamics of the tissue *after* it has been stimulated, and while it is undergoing active depolarization and repolarization. As explained in the next paragraph at column 2, lines 48-51, it is therefore necessary that the ETC signal be delivered during the effective refractory period of the heart, which may be arrhythmogenic. It is precisely because this refractory period will be arrhythmogenic that the blanking interval is used in conventional pacers immediately following the stimulation pulse, to avoid sensing a "meaningless" signal.

The Examiner cited the language at column 20, line 26 of the Mika et al reference as, according to the Examiner, teaching reconstruction of an IEGM signal from one of the multiple chambers in the blanking interval following delivery of one of the pacing pulses. This passage does not make any mention of the blanking

interval, however, if a signal is being sensed at the time described in the passage at column 20, line 26, it is almost certainly not within the blanking interval, because at that time, by definition, no signal is being sensed, for the aforementioned reasons. Moreover, this later passage makes clear that the passage referred to by the Examiner does not involve reconstructing a portion of a signal that is "missing" due to the occurrence of a blanking interval, but is for the purpose of removing artifacts that exist in the sensed signal due to the presence of the ETC signal. This is explained at the bottom of column 19, wherein it is stated that the large deflection in the sensed signal represents an ETC signal-induced artifacts, which can cause clipping in the amplifier units used in the sensing circuit. The passage cited by the Examiner at column 20 is for the purpose of solving this problem, as explicitly stated in the first sentence at the top of column 20.

Therefore, the most that can be set of the Mika et al reference is that it teaches, in a cardiac stimulator, subjecting a sensed signal, obtained any time other than during the blanking interval, to processing to remove signal artifacts therefrom, caused by the *presence* of the ETC signal, rather than due to the *absence* of a signal during the blanking interval.

This "signal reconstruction," (if that is what it is) therefore has nothing to do with the inability to sense an IEGM signal in one chamber due to the occurrence of a blanking signal being generated in association with stimulation of a different chamber.

Moreover, as the Examiner has noted the Mika et al reference is primarily directed to undertaking the aforementioned signal processing for signals associated with one chamber of a heart, but includes a general statement that the techniques described therein can be used in a multi-chamber pacer. Even if the teachings of the

Mika et al were extended to multi-chamber pacing, this would merely mean that, for each chamber, the aforementioned signal processing described in Mika et al is undertaken. As noted above, this has nothing to do with sensing a signal in one chamber during a blanking interval that has been generated due to stimulation in a different chamber. Therefore, despite this general, non-detailed statement in the Mika et al reference regarding the use of the teachings thereof in multi-chamber pacing, this still does not provide a person of ordinary skill in the field of cardiac stimulator design with any teaching, motivation or guidance to solve the problem to which the subject matter of the present application is directed.

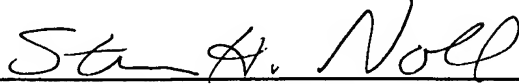
Claims 1, 3 and 4, therefore, would not have been obvious to a person of ordinary skill in the field of cardiac stimulator design, based on the teachings of Mika et al.

Claims 1-3 and 6-10 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting based on claims 1-12 of copending application Serial No. 10/813,776. A Terminal Disclaimer is submitted which overcomes this provisional double patenting rejection. As required under MPEP Section 804.02, Section II, fifth paragraph, Applicants are also submitting a Terminal Disclaimer in Serial No. 10/813,776.

Applicants note with appreciation that claims 5, 11 and 12 were stated to be allowable if rewritten in independent form. In view of the traversal of the rejection of claim 1 based on the Mika et al reference, however, those claims have been retained in dependent form at this time.

All claims of the application are submitted to be in condition for allowance,
and early reconsideration of the application is therefore respectfully requested.

Submitted by,



(Reg. 28,982)

SCHIFF, HARDIN LLP
CUSTOMER NO. 26574
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606
Telephone: 312/258-5790
Attorneys for Applicant(s).

CH1\ 4392390.1